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Promotion and protection of human rights: human rights questions, including alternative approaches for improving the effective enjoyment of human rights and fundamental freedoms

Cultural rights

Note by the Secretary-General

The Secretary-General has the honour to transmit to the General Assembly the report of the Special Rapporteur in the field of cultural rights, Farida Shaheed, submitted in accordance with Human Rights Council resolution 28/9.

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Report of the Special Rapporteur in the field of cultural rights

Summary

In the report, the Special Rapporteur addresses the implications of patent policy for the human right to science and culture. She reaffirms the distinction to be made between intellectual property rights and human rights, emphasizing that the right to the protection of the moral and material interests of authors does not necessarily coincide with the prevailing approach to intellectual property law. There is no human right to patent protection. The right to protection of moral and material interests cannot be used to defend patent laws that inadequately respect the right to participate in cultural life, to enjoy the benefits of scientific progress and its applications, to scientific freedoms and he right to food and health and the rights of indigenous peoples and local communities.

Patents, when properly structured, may expand the options and well-being of all people by making new possibilities available. Yet, they also give patent-holders the power to deny access to others, thereby limiting or denying the public's right of participation to science and culture. The human rights perspective demands that patents do not extend so far as to interfere with individuals' dignity and well-being. Where patent rights and human rights are in conflict, human rights must prevail.

Whereas from the perspective of trade law, exclusions, exceptions and flexibilities under international intellectual property law, such as the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights, remain optional, from the perspective of human rights, they are often to be considered as obligations.

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I. Introduction

1. The present report is the second of two consecutive studies by the Special Rapporteur in the field of cultural rights on intellectual property policies and the right to science and culture. The first report (A/HRC/28/57 and Add.1 and 2) focused on how copyright policy interfaces with the protection of authors' moral and material interests, and the right of everyone to benefit from scientific and cultural creativity. The present report addresses patent policy.

2. The relationship between human rights and intellectual property is important and complex. The last decades have witnessed growing concern that the design and implementation of intellectual property laws may undermine the enjoyment of human rights. A notable example of this interaction is the tension between pharmaceutical patents and the affordability of medicines with respect to the right to health. Patent policies in the areas of agriculture, energy-saving and climate-change mitigation technologies are sometimes feared to threaten the enjoyment of the rights to food and to a safe and sustainable environment.

3. The tension between patent protection and broad public access is common to all fields of essential technologies, beyond the areas of health, food or the environment. Innovations essential for a life with dignity should be accessible to everyone, and potential implications of scientific advances likely to have a significant impact on human rights require attention, for example, in the field of energy, information and communication technologies, nanotechnology and synthetic biology (see A/HRC/20/26, paras. 26 and 29).

4. The central challenge is "to recognize and reward human creativity and innovation, and, at the same time, to ensure public access to the fruits of those endeavours."[1] Well-designed patent laws and policies play a vital role in encouraging private investment in scientific research and development, making an important contribution to scientific progress and human well-being. In order for the international patent system to continue to serve its fundamental purpose of encouraging innovation and promoting dissemination and transfer of technology, the right balance is required between the rights of technology holders and the rights of technology users for the benefit of society as a whole (see A/HRC/20/26, para. 58).

5. The right to science and culture, understood as encompassing the rights to take part in cultural life, to enjoy the benefits of scientific progress and its applications, and to benefit from the protection of the moral and material interests resulting from scientific, literary or artistic productions of which a person is the author, offers a particularly promising framework for reconciling the tensions between human rights and intellectual property laws.[2] Although the human right to science and culture does not establish a human right to patent protection, it does provide a human rights framework within which to consider patent policy.

6. The Special Rapporteur convened several meetings in 2014 to elicit the views of States and other stakeholders on the impact of intellectual property regimes on the enjoyment of the right to science and culture: an open consultation on 6 June

[1] See Laurence R. Helfer and Graeme W. Austin, *Human Rights and Intellectual Property: Mapping the Global Interface* (New York, Cambridge University Press, 2011).

[2] See Lea Shaver, "The right to science and culture", *Wisconsin Law Review*, vol. 2010, No. 1 (2010); available from http://ssrn.com/abstract=1354788.

(Geneva), and experts' meetings on 10 and 11 June (Geneva) and 28 and 29 October (New York University and Yale University) (see A/HRC/28/57, annex). Additional experts contributed through correspondence (see A/HRC/28/57, annex). Contributions from various States and stakeholders are available online. The Special Rapporteur is grateful to all those who contributed.

II. International and national legal framework

A. Relevant human rights provisions

7. The right to science and culture is recognized in several human rights instruments, in particular the Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights. It is also enshrined in regional human rights conventions and in many national constitutions, often alongside a commitment to the protection of intellectual property.

8. Article 27 of the Universal Declaration of Human Rights provides for the right of everyone (1) "freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits." and to (2) "the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author." This dual aspect of participation and protection is included in all later articulations of the right to science and culture, in particular article 15, paragraph 1, of the International Covenant on Economic, Social and Cultural Rights, with article 15, paragraphs 2, 3 and 4, adding the touchstone principles of "conservation, development, and diffusion" of science and culture, the freedom indispensable for scientific research and creative activity, and the importance and desirability of international cooperation in the scientific and cultural fields.

9. The Committee on Economic, Social and Cultural Rights has elaborated on some aspects of the right to science and culture, through general comment 21 on the right to take part in cultural life (see E/C.12/GC/21) and general comment 17, on the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which she or he is the author (see E/C.12/GC/17).

10. General comment 17 distinguishes between intellectual property rights and human rights, emphasizing that the moral and material interests of authors do not necessarily coincide with the prevailing approach to intellectual property law. The Committee instead ties the "material interests" of authors to the ability of individual creators to enjoy an adequate standard of living, avoiding the conflation of this term with property rights or rights of exclusion, especially when held by corporations rather than individual creators.

11. General comment 17 emphasizes States' obligations to strike an adequate balance between protecting the moral and material interests of authors and other human rights under the International Covenant on Economic, Social and Cultural Rights, including balancing the private interests of authors with the public's interest in enjoying broad access. States should therefore ensure that their legal and other regimes for the protection of the moral and material interests of authors constitute no impediment to States' ability to comply with their core obligations in relation to

other human rights. The Committee stressed that intellectual property is a social product with a social function and that States have a duty to prevent unreasonably high costs for access to essential medicines, plant seeds or other means of food production that could undermine the rights of large segments of the population to health and food (see E/C.12/GC/17, para. 35).

12. The right of everyone to enjoy the benefits of scientific progress and its applications, enshrined in article 15, paragraph 1, of the International Covenant on Economic, Social and Cultural Rights, has been addressed by the Special Rapporteur (see A/HRC/20/26). The Special Rapporteur defined the normative content of this right as including (a) access to the benefits of science by everyone without discrimination; (b) opportunities for all to contribute to the scientific enterprise and freedom indispensable for scientific research; (c) participation of individuals and communities in decision-making; and (d) an enabling environment fostering the conservation, development and diffusion of science and technology. She emphasized that the spirit of the human right to science and culture recognizes human knowledge as a global public good and recommended that States guard against promoting the privatization of knowledge to an extent that deprives individuals of opportunities to take part in cultural life and enjoy the fruits of scientific progress (see A/HRC/20/26, paras. 25 and 65).

13. Article 15, paragraph 3, of the International Covenant on Economic, Social and Cultural Rights stipulates that States must respect the freedom indispensable for scientific research and creative activity. Freedom of scientific research means ensuring that the scientific enterprise remains free of political and other interference, while guaranteeing the highest standards of ethical safeguards by scientific professions. It encompasses the right of everyone to participate in the scientific enterprise without discrimination (see A/HRC/20/26, paras. 39 and 42), including the ability to research, to participate in and to improve already existing knowledge, technologies and processes.

14. While the International Covenant on Economic, Social and Cultural Rights provides for the "progressive" realization of rights and recognizes the problems arising from limited resources, it imposes the continuing obligation to take deliberate and concrete measures for the full implementation of these rights. States have the immediate obligation to guarantee that rights are exercised without discrimination and to ensure that their legal frameworks do not inappropriately burden the enjoyment of rights.

B. International and national regulation of patent policy

15. Patent law is territorial and thus largely regulated at the national level. During the patent protection term, unless the patent-holder's permission is obtained, third parties are generally prohibited from making, using, offering for sale, selling or importing any product incorporating that technology or from using the patent-protected process for making a product for commercial purposes. Various mechanisms may be built into national patent systems to prevent abuse and misuse of such exclusive rights.

16. Multilateral, regional and bilateral treaties greatly limit the discretion of States. Treaties elevating standards of patent protection are of concern to many States, in particular developing countries.

17. The international perspective regarding patent protection has shifted over time. During the nineteenth century, the desirability of patent protection was not uniformly viewed even among industrialized countries. During the 1960s and 1970s, newly independent States and developing countries widely concurred on the need to limit patent protection in order to promote technology transfer at affordable prices. Medical and agricultural technologies were excluded from the patent regimes of many countries, including some developed countries, up until the 1990s. Since the 1970s, multinational corporations have lobbied their Governments to push for more muscular intellectual property protection abroad, despite the opposition of developing countries. Although such efforts originally focused on the World Intellectual Property Organization (WIPO), certain industries pushed for Governments to harmonize minimum standards of intellectual property protection in the Uruguay Round of the General Agreement on Tariffs and Trade negotiations. The objective was to seek broad geographic coverage of the protection and the effective enforcement of intellectual property rights.[3]

18. By 1994, an internationally binding approach to intellectual property rights and their enforcement, based on high standards of protection, had prevailed, notably through the negotiation of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Article 27.1 of the TRIPS Agreement specifies that patents shall be available for any invention, whether a product or process, in all fields of technology, provided that it is new, involves an inventive step and is capable of industrial application.

19. The TRIPS Agreement marks a departure from the Paris Convention for the Protection of Industrial Property of 1883. It establishes patent protection for a minimum term of 20 years, ignoring the diversity of national needs (see TRIPS Agreement, art. 33). The Paris Convention, and the subsequent agreements that built upon it, gave countries sufficient flexibility to adapt their intellectual property regime in the light of their socio-economic needs and objectives and allowed States to exclude strategic sectors, such as the pharmaceutical and agrochemical industries, from patentability and to determine the length of protection (A/HRC/11/12, para. 24).

20. The TRIPS Agreement requirements apply to all World Trade Organization (WTO) members, although least developed countries have until at least 2021 to come into compliance, thanks to extended transition periods. It is enforceable through the decisions of the WTO Dispute Settlement Body, backed by the possibility of trade sanctions.

21. Despite considerable limitations, the TRIPS Agreement includes certain safeguards providing some flexibility to limit or even exclude patent protection, including extended transition periods for developing countries. Consequently, corporations and some developed States "have pushed since its inception for a wider and stronger set of standards through add-on agreements, often called TRIPS-Plus treaties or provisions. Such agreements would, for example, limit opposition to patent applications; prohibit national regulatory authorities from approving generic medicines until patents have expired; maintain data exclusivity, thereby delaying the approval of biogeneric drugs; and require new forms of protection, such as

[3] See Carlos Correa, "The current system of trade and intellectual property rights", *European Yearbook on International Economic Law*, vol. 7, forthcoming.

anti-counterfeiting measures."[4] Furthermore, border enforcement measures have been used to seize legitimate generic medications in transit.[5]

22. According to the Special Rapporteur on the right to health, the ultimate goal of developed countries in various bilateral and multilateral free trade agreements remains the universal harmonization of intellectual property laws according to their own higher intellectual property standards and enforcement measures (A/HRC/11/12, para 23). Developing countries, for their part, generally try to resist this trend.

23. There are several claimed benefits of granting patent rights and implementing the TRIPS Agreement: offering companies incentives to invest in the expensive processes of developing new technologies and bringing them to market; rewarding human creativity, especially in areas that demand massive investment with no guarantee of an effective financial return; obliging inventors to disclose their findings; and developing new technologies.

24. These claims need to be carefully weighed, taking into consideration the various interests at stake and the technologies in question (for example, some require expensive research, some do not). The effects of intellectual property rights are strongly context-dependent. It is not possible to expect the same outcomes in countries with very different levels of technological capacity and industrial profile. Many academic and other analyses strongly reject the premise of the TRIPS Agreement that minimum standards of protection are equally beneficial for countries with diverse levels of socio-economic and technological development.[3]

25. Patent offices ascertain whether patent applications are compatible with the precise standards of patentability under national law, which vary, sometimes significantly, from jurisdiction to jurisdiction within the TRIPS Agreement parameters. There are concerns relating to the low standard of inventiveness applied in some countries, which has enabled "the grant of a large number of patents on minor or trivial developments, often aggressively used to artificially extend the duration of protection and to block legitimate competition".[6]

26. The administrative challenge of "patent quality", ensuring that patents are issued only where justified, is significant.[7] Aggressive patenting practices exploit such administrative weaknesses. The practice of patent "trolling" and the proliferation of patents thickets, where the right-holder's aim is not to manufacture any product or use the process, but to launch frivolous lawsuits and collect fees based on ambiguous patent claims or exclude others from developing competing

[4] See Joseph E. Stiglitz, Arjun Jayadev, "India's patently wise decision", 8 April 2013; available from www.project-syndicate.org/commentary/the-impact-of-the-indian-supreme-court-s-patent-decision-by-joseph-e--stiglitz-and-arjun-jayadev.

[5] Joint United Nations Programme on HIV/AIDS (UNAIDS) and United Nations Development Programme (UNDP), *The Potential Impact of Free Trade Agreements on Public Health* (Geneva, UNAIDS, 2012); Mônica Steffen Guise Rosina and Lea Shaver, "Why are generic drugs being held up in transit? Intellectual property rights, international trade, and the right to health in Brazil and beyond", *Journal of Law, Medicine, and Ethics*, vol. 40, No. 2 (Summer 2012).

[6] United Nations Conference on Trade and Development (UNCTAD) and International Centre for Trade and Sustainable Development, *Resource Book on TRIPS and Development* (New York, Cambridge University Press, 2005).

[7] See R. Polk Wagner, "Understanding patent-quality mechanisms, *University of Pennsylvania Law Review*, vol. 157, No. 6 (2009).

technologies, obstruct further development and dissemination of technology. High numbers of low-quality patents hinder research, legitimate competition and access.

27. Of concern is the patenting of second or third (etcetera) uses of products, in particular medicines, and more generally the practice of ever-greening, which, through minor or artificial improvements, extends the life of patents beyond the time limit of 20 years. The appropriation of scientific knowledge through patents (such as patents on genes) and the patenting of discoveries (that is, pre-existing information versus inventions); of frivolous innovations; and the practice of misappropriation of indigenous and local communities' innovations through patents is equally of concern.

III. Inventors under article 15, paragraph 1 (c), of the International Covenant on Economic, Social and Cultural Rights

A. Moral and material interests of inventors and discoverers

28. A strongly debated question is whether "authors" in article 15, paragraph 1(c) of the International Covenant on Economic, Social and Cultural Rights includes inventors and scientific discoverers, and whether the latter, like "authors", enjoy the right to the protection of the moral and material interests resulting from their scientific production, and if so, with what meaning.

29. Some commentators, arguing strongly against such an extension, stress that the right to protection of authorship is historically and uniquely related to expressive creativity and copyright protection. In contrast, patent law is based on considerations of economic incentives for innovation, not on the concept of inventions as an expression of the personality of the inventor.[8] Additionally, commentators are concerned that expanding the recognition of "moral and material interests" to the field of inventions and patents may create additional barriers to the human rights to health and food, and the rights of indigenous peoples.[9]

30. The drafters of human rights instruments may have shied away from including protection of inventions within the scope of the human right to science and culture. The Universal Declaration of Human Rights drafting committee initially considered a text that included explicit mention of inventors, but the finally adopted text refers only to authors (see E/CN.4/57). Similarly, while the American Declaration on the Rights and Duties of Man includes the protection of moral and material interests as regards inventions as well as any literary, scientific or artistic works,[10] inventions were dropped from the Additional Protocol to the American Convention on Human

[8] See Rochelle Cooper Dreyfuss, "Patents and human rights: where is the paradox?", Law and Economics Research Paper, No. 06-38, (New York University, School of Law, 2006); available from http://papers.ssrn.com/sol3/papers.cfm?abstract_id=929498.

[9] See Jerzy Koopman, "Human rights implications of patenting biotechnological knowledge", in *Intellectual Property and Human Rights*, Paul L. C. Torremans, ed. (Alphen aan den Rijn, The Netherlands, Kluwer Law International, 2008); Peter K. Yu, "Reconceptualizing intellectual property interests in a human rights framework", *University of Davis Law Review*, vol. 40, 2007.

[10] See Organization of American States, American Declaration of the Rights and Duties of a Man, article XIII (1948).

Rights in the Area of Economic, Social and Cultural Rights of 1988 (The Protocol of San Salvador).

31. In contrast, other commentators believe that the right to protection of the moral and material interests of authors extends to inventors and, therefore, that the human right to protection of authorship requires protection of the interests of individuals and communities who contribute to technological innovation as one form of human creativity.[11]

32. The Committee on Economic, Social and Cultural Rights considers that the term "author" includes a "creator" of scientific innovations (E/C.12/GC/17, paras. 7 and 9). This expansive reading, however, has been set within specific parameters and safeguards, which deserve to be restated. Article 15, paragraph 1(c) of the International Covenant on Economic, Social and Cultural Rights does not recognize a human right to protection of intellectual property along the lines set out by intellectual property treaties. The equation of intellectual property regimes with the human right to protection of the moral and material interests of authors is false and misleading. Whereas the human right to benefit from the protection of the moral and material interests resulting from one's scientific, literary and artistic productions safeguards the personal link between authors and their creations and between peoples, communities or other groups and their collective cultural heritage, as well as their basic material interests, which are necessary to enable authors to enjoy an adequate standard of living, intellectual property regimes primarily protect business and corporate interests and investments. In addition, contrary to intellectual property rights, human rights are inalienable. The entitlements of legal entities under the intellectual property treaties, because of their different nature, are not protected at the level of human rights (E/C.12/GC/17, paras. 2, 3 and 7).

33. The Special Rapporteur acknowledges that the human right to property has sometimes been used as a basis for patent protection, in particular within the European human rights system.[12] The provisions on the right to property oblige States to comply with the patent rules that have been legally adopted, but do not mandate any particular approach to the design of patent laws and policy; neither do they provide guidelines regarding the form that the protection of intellectual property should take.[13] Additionally, the right to property is subject to very far-reaching government power to regulate its use in line with its social function. Under the jurisprudence of the European Court of Human Rights, the rejection of a particular patent application or the issuance of a compulsory license in the interests of public health might be viewed as an interference with the right to property, but is highly unlikely to be viewed as a violation, unless done in an arbitrary or capricious way.[13]

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[11] See Estelle Derclaye, "Intellectual property rights and human rights: coinciding and cooperating", in *Intellectual Property and Human Rights*, Paul L. C. Torremans, ed. (Alphen aan den Rijn, The Netherlands, Kluwer Law International, 2008).

[12] See Charter of Fundamental Rights of the European Union, article 17 (2); article 1 of the first Protocol to the European Convention on Human Rights and Fundamental Freedoms.

[13] See *Anhueser-Busch Inc. v. Portugal*, Application No. 73049/01, 44 European Court of Human Rights, Report 42 (holding that refusal to register a trademark "amounts to interference with the applicant company's right of property" but declining to find that the right was violated); and *Smith Kline and French Laboratories Limited. v. The Netherlands*, Application No. 12633/87 of the European Court of Human Rights, Decisions and Reports 66 of October 1990 (holding that national issuance of a compulsory license "constituted a control of the use of property" and upholding the compulsory license as justifiable.

34. In conclusion, the term "authors" within the right to science and culture can be interpreted to include inventors and scientific discoverers. Under this interpretation, individuals and communities are entitled to protection of the moral and material interests related to the inventions with which they have a strong personal link, similar to the link between an author in the traditional sense and their creative work of authorship. This protection must ensure respect for this personal link, and promote the individual or community's enjoyment of an adequate standard of living. This right does not provide patent holders' grounds to challenge patent rules as providing inadequate protection of their financial or commercial interests. Nor can the right to protection of moral and material interests be used by States to defend patent laws that inadequately respect the right to science and culture.

B. Rights of indigenous peoples and local communities

35. There is a "defensive" and a "positive" approach in using intellectual property to protect the biocultural heritage of indigenous peoples and local communities. The defensive approach seeks to prevent the patenting of (or the acquisition of other intellectual property rights over) traditional knowledge by third parties, in violation of the rights and/or interests of indigenous and local peoples. The positive approach seeks to leverage indigenous and local intellectual property to provide indigenous and local groups with greater control over their knowledge assets.

36. The United Nations Declaration on the Rights of Indigenous Peoples states that indigenous peoples have the right to maintain, control, protect and develop their intellectual property (see art. 31, para. 1, of the Declaration). It differs from the Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights in that it specifically enunciates a right to intellectual property, rather than to the protection of moral and material interests. The discussion has come to be framed around traditional cultural expressions (such as artwork, narratives, rituals and music), traditional knowledge (such as indigenous medical and agricultural know-how and technologies) and genetic resources (which might be plant, animal or microbial biological genetic material).

37. Several motivations underlie this right, including the right of indigenous peoples to self-determination, their right to maintain and develop their culture and their struggle for cultural survival. Some indigenous and local communities consider it vital to keep certain forms of knowledge from public disclosure, to be used only by persons and in ways that are appropriate according to customary laws and practices, and never commercially exploited. Simultaneously, some peoples wish to take advantage of the commercial potential of licensing products based on their traditional knowledge and genetic resources. Additionally, indigenous and local communities may object to the improper patenting of their natural or genetic resources and associated traditional knowledge and practices in ways that deny appropriate credit and ownership to the true source of the resource or knowledge.

38. International and national intellectual property regimes have historically failed to adequately take into account the concerns of indigenous peoples and local communities. The interests in maintaining control over non-commercial, communally created and historically rooted cultural assets tend to fall through the cracks of intellectual property regimes. For example, traditional knowledge that has been made available to the public is generally regarded as being in the public

domain and therefore free for anyone to use, and there is enormous variation in the ways that States have sought to give effect to indigenous rights connected to patent policy.

39. In 1995, the Principles and Guidelines for the Protection of the Heritage of Indigenous Peoples were presented to the Commission on Human Rights (see E/CN.4/Sub.2/1995/26). Of note are the principles that indigenous peoples' ownership and custody of their heritage must continue to be collective, permanent and inalienable; that the free, prior and informed consent of the traditional owners or custodians must be a precondition to any agreements for the recording, study, use or display of indigenous peoples' heritage; and that peoples concerned must be the primary beneficiaries of any commercial application of their heritage (see principles 5, 9 and 10).

40. The 1992 Convention on Biological Diversity and its 2010 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization contain provisions on traditional knowledge associated with genetic resources held by indigenous and local communities. States must ensure these communities' prior informed consent, as well as fair and equitable benefit-sharing, keeping in mind community laws and procedures and customary use and exchange.[14]

41. "Protection" of traditional knowledge or traditional cultural expressions in the intellectual property sense means ensuring that the intellectual innovation and creativity embodied in traditional knowledge and traditional cultural expressions are not wrongly used. It may include protection against misuse or misappropriation, such as copying, adaptation or use by unauthorized third parties, equitable compensation schemes and protection against unfair competition. Requiring inventors to include and make public relevant information about important inputs obtained from communities can be used as a protective mechanism. Such disclosure can serve as a check against misappropriation, and help to determine the scope of benefit sharing due to indigenous groups.[14]

42. "Protection" is therefore different from "preservation" and "safeguarding," which emphasize the identification, documentation, transmission, revitalization and promotion of cultural heritage in order to ensure its maintenance or viability. "Protection," "preservation" and "safeguarding" are collectively reinforcing and need to be implemented with such awareness, taking into consideration that indigenous and local knowledge systems are in constant evolution.

43. The recognition of the interests of indigenous peoples to maintain, control, protect and develop their intellectual property over their cultural heritage (traditional knowledge/traditional cultural expressions) falls within the wider human rights framework. Accordingly, it too is subject to limitations established to ensure equitable and universal access to the benefits of scientific advancement. For example, important medicines might be classified as traditional knowledge. The right to the benefit of scientific advancement in this context might require that the traditional knowledge be made available to others for the fulfilment of their right to health.

[14] See UNCTAD, "The Convention on Biodiversity and the Nagoya Protocol: Intellectual Property Implications: A Handbook on the Interface between Global Access and Benefit Sharing Rules and Intellectual Property" (Geneva, 2014).

44. Under article 46, paragraph 2, of the Declaration on the Rights of Indigenous Peoples, the exercise of the rights set forth in the Declaration are subject only to such limitations as are determined by law and in accordance with international human rights obligations. Any such limitations shall be non-discriminatory and strictly necessary solely for the purpose of securing due recognition and respect for the rights and freedoms of others and for meeting the just and most compelling requirements of a democratic society. Such limitations can be problematic, however, if they are justified by reference to the interest of a mainstream society that otherwise does not recognize indigenous interests. In such cases, limitations can be misused to the detriment of indigenous communities.

45. While the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore has undertaken negotiations for an agreement or an international legal instrument(s) that will ensure the effective protection of genetic resources, traditional knowledge and traditional cultural expressions, progress seems uncertain.

IV. Patent policy and the right to science and culture: identified tensions

46. Article 15, paragraph 15 1(c), recognizes the human rights of scientific creators, but does not require the patenting of inventions. Simultaneously, it recognizes the right of everyone "to enjoy the benefits of scientific progress and its applications", a phrase that includes technologies that may be protected by patents.

47. Patents, when properly structured, expand the options and well-being of all people by making available new possibilities. Yet, they also give patent owners the power to deny others access, thereby limiting or denying the public's right of participation to science and culture. The human rights perspective demands that patents do not extend so far as to interfere with individuals' dignity and well-being. This may be the case, for example, when the patent-holder's property right is so strong as to make compulsory licensing of medicines impracticable or unduly cumbersome. Various exceptions and limitations on patents are required to protect the right of participation in culture, science and technology.

A. Impact of patent policy on ensuring access to essential technologies

48. Technology, when utilized well, has an immense potential to improve human lives in all aspects. Indeed, the growth of "useful knowledge", particularly the application of scientific progress through technology, is the fundamental driver of rising standards of living.[15] Unfortunately, not everyone is equally able to enjoy the benefits of new technologies or participate in this process.

49. In her thematic report on the right to science, the Special Rapporteur stressed that innovations essential for a life with dignity should be accessible to everyone, in particular marginalized populations. From a human rights perspective, mechanisms

[15] See Joel Mokyr, *The Gifts of Athena: Historical Origins of the Knowledge Economy* (Princeton, New Jersey, Princeton University Press, 2002).

are needed to protect the public interest wherever a particular technology is critical to human welfare, as might be the case in areas of health, agriculture or housing.

50. Patents generally enable patent-holding firms to charge higher prices, raising concerns about access to essential technologies, including medicines and seeds. Other undesirable effects may include insufficiency of supply to meet the need owing to the inadequacy of the sole producer; financial pressure put on social security systems; or a lack of competitive pressure to improve the product's quality, lower its cost or adapt the product to serve alternative markets.

51. Pharmaceutical products, especially HIV medicines, are a particularly well-known example of this tension between exclusive production and broad public access, as mentioned by the Special Rapporteur on the right of health (see A/HRC/11/12, para. 20). According to the Global Commission on HIV and the Law, current international intellectual property laws have failed to promote innovation to treat diseases that primarily affect low- and middle-income countries. The Commission called upon the United Nations to propose and develop a new intellectual property regime for medicines, consistent with human rights obligations. It also called upon WTO to suspend the requirements of the TRIPS Agreement, as they pertain to essential pharmaceutical products in both low- and middle-income countries.[16] Countries have found it necessary to issue compulsory licenses on patented drugs and vaccines to respond to urgent public health needs.

52. The Special Rapporteur on the right to food identified the increasing application of intellectual property regimes to plant varieties and seeds as a significant threat to food security, particularly for the poor (see A/64/170). Overlooking farmers' informal systems, intellectual property regulations focus exclusively on the commercial seed system. National rules adopted to implement these regimes frequently prohibit even small farmers and public institutions from sharing, replanting and improving seeds covered by patents and plant varieties.[16] Hence, "an excessive protection of monopoly rights over genetic resources can stifle progress in the name of rewarding it". Such an approach undermines the livelihoods of small farmers, traditional and not-for-profit crop innovation systems, agro-biodiversity as a global public good and the planetary food system as a whole. It is crucial to recognize that (at least) two parallel agricultural systems exist, and should continue to exist: the commercial seed system and the farmers' seeds (landraces) or informal systems.[17]

53. Other areas of scientific innovation also have a significant impact on human rights, such as energy, information and communication technologies, nanotechnology and synthetic biology (see A/HRC/20/26, paras. 26 and 29).

54. It is important to address the gaps and resulting discriminations between those with and without access to technologies, in the enjoyment of their right to participate in the political, social, economic and cultural life of the society. "Innovations that give power to those who have access to them, under conditions that make those who lack them vulnerable, can be used to dominate and to exploit,

[16] See UNDP, "Global Commission on HIV and the law: risks, rights and health" (New York, 2012), recommendation 6.1.

[17] Olivier De Schutter, "The right of everyone to enjoy the benefits of scientific progress and the right to food: from conflict to complementarity", *Human Rights Quarterly*, vol. 33, No. 2 (May 2011).

exacerbating existing injustices and perhaps even creating new ones. (...) Lack of access could literally create a new class of disabled persons — individuals who are unable to participate effectively in what might be called the dominant cooperative scheme" and whose "capacities will not satisfy the demands of what will have become 'normal' human life".[18]

55. The conjoined human right to science and culture should be understood as including a right to have access to, use and further develop technologies in self-determined and empowering ways. New scientific knowledge and innovations increase available options, thereby strengthening people's capacity to envisage a better future for which access to specific technologies may sometimes be pivotal (see A/HRC/20/26, para. 20). Interrogating the impact of patent policy on the right to science cannot be dissociated from interrogating its impact on the right to participate in cultural life and to pursue specific ways of life, such as in the case of small farmers. Access to the benefits of scientific progress not only allows improving one's socio-economic situation, but also gives the opportunity for meaningful participation in the life of local, national or international communities. One example is new information communication technologies, which not only influence culture, but are also becoming an intrinsic part of culture as everyday practice (see A/HRC/20/26, para. 19).[19]

B. Impact of patent policy on the direction of scientific research

56. Patent policies and practices may divert research priorities away from matters of greatest public concern. Where the technological needs of the rich and poor overlap, technologies developed for sale to wealthy segments of society will also benefit the poor. But when needs do not coincide, intellectual property may be ineffective for stimulating the necessary research and development,[20] for example, to treat diseases primarily experienced by the poor in developing countries,[21] or to address the needs of persons with disabilities.

57. Alternative mechanisms have long existed alongside patents to stimulate research. These include tax incentives for corporate investments in research and development, public funding for scientific research, government purchasing, prize competitions and advance market commitments. These mechanisms avoid two liabilities of the patent-focused approach to research and innovation: they can be tied to social benefit rather than market demand, and they do not require legal restrictions on the diffusion of the resulting technologies.[21] These approaches have downsides too, however, which the patent system resolves. For example, public funding is not a realistic solution for all sciences. Alternative mechanisms need to

[18] See Allen Buchanan, "Justice in innovation and human rights in and to science", discussion paper presented at the Human Rights and Science: Mapping the Issues workshop, Fribourg, Switzerland, 2014.

[19] See also United Nations Educational, Scientific and Cultural Organization, "The right to enjoy the benefits of scientific progress and its applications" (Paris, 2009).

[20] See Amy Kapczynski, "The cost of price: why and how to get beyond intellectual property internalism", *UCLA Law Review*, vol. 59, No 4 (2012).

[21] See World Health Organization, *Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation, and Public Health* (Geneva, 2006).

be carefully crafted to ensure that they meet their purpose, especially in areas of essential technologies where the patent system does not work well.

58. A worrisome trend is the expanding roles of patent-seeking in scientific research at universities and public research institutions. The result is that the fruits of publicly funded scientific research are often transferred to exclusive private ownership. Of equal concern is the change in the culture surrounding university research, away from an activity conducted for the public good and human advancement towards an activity valued only for its potential commercial application.

59. Another concern is that rights-holders may exclude competitors from producing an improved dependent technology. A third-party who finds a way to further improve a patented technology may patent her or his improvement, yet be unable to sell the improved technology without a license from the patentee of the underlying technology. Ideally, both parties would conclude an agreement and practice cross-licensing. Should this not occur, however, valuable technological improvements may fail to become commercially available. Many countries allow for compulsory licensing to overcome such situations, thereby promoting the public's right to benefit from technological improvements and the improver's right to benefit from their invention.

60. One dimension of this issue relates to the situation of small farmers across the world, and the recognition of their right to continue improving their seeds. The TRIPS Agreement requires States to protect plant varieties "either by patents or by an effective sui generis system or by any combination thereof". Some States believe that this is restricted to the International Union for the Protection of New Varieties (UPOV) system, which has been criticized for its negative impact on small farmers, in particular in developing countries.[22] In fact, there is a wide range of possible other effective sui generis systems that may be adapted to national circumstances.[23]

V. Asserting the right to science and culture in patent policy: the way forward

61. Article 7 of the TRIPS Agreement provides that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations". The word "should" indicates that such effects do not automatically result from intellectual property protection, and that countries should frame their legislation with the aim of reaching these effects.

62. As underlined by commentators, "it is often possible to expand the protection of private rights holders and increase their investment returns, but this expansion of

[22] See Thomas Braunschweig and others, "Owing seeds, accessing food: a human rights impact assessment of UPOV 1991 based on case studies in Kenya, Peru and the Philippines" (Zurich, Berne Declaration, 2014).

[23] See Hans Morten Haugen, "Inappropriate processes and unbalanced outcomes: plant variety protection in Africa goes beyond UPOV 1991 requirements", *Journal of World Intellectual Property* (forthcoming).

rights may have an adverse impact on the welfare of a wider public. The objective of intellectual property rights law is not to provide the maximum possible return to rights holders, but to strike the proper balance of private and public interests".[6] States must ensure that their patent laws are well-designed to promote the right of the public to participate in scientific progress, both through universal access to essential technologies and by eliminating or overcoming barriers to scientific research and technological development.

A. Promoting the right to science and culture through exclusions, exceptions and flexibilities

63. Several flexibilities to patents can be used by national Governments when implementing multilateral treaties. These are key to striking the proper balance between private and public interests, and to ensuring respect for a wide range of human rights. Yet, their effectiveness is limited by the infrequency of their use, for reasons ranging from capacity constraints to commercial and political pressures against their use.[24]

64. Article 27.1 of the TRIPS Agreement relates to patentability requirements. It leaves States significant freedom to determine the degree of strictness to be applied for judging novelty, the inventive step and industrial applicability. These terms are not further defined in the Agreement. The World Bank has suggested that developing countries could set high standards for the inventive step, thereby preventing routine discoveries from being patented.[6]

65. Exclusions from patentability preclude a given subject matter from protection and can lead to the non-granting of a patent.[6] For example, under article 27 of the TRIPS Agreement, States may exclude from patentability diagnostic therapeutic and surgical methods for the treatment of humans and animals. States may also exclude plants and animals other than microorganisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes (however plant varieties shall be protected either by patents or by an effective sui generis system or a combination thereof).

66. This latter point has raised considerable concern, in particular among developing countries, as article 27, while providing some flexibility, simultaneously obliges States to protect microorganisms, certain biotechnological processes and plant varieties. Specific concerns relate to the protection of biological resources and traditional knowledge, and the need to reconcile article 27 with the Convention on Biological Diversity, particularly on the free, prior informed consent of indigenous and local communities and benefit sharing. The patenting of plant variety raises concerns about the impact on farming practices, genetic diversity and food security.[6]

67. Under article 30 of the TRIPS Agreement, States may provide limited exceptions to the exclusive rights conferred by a patent, allowing use by third parties, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the interests of the patent owner, taking into account the legitimate interest of third parties. Such

[24] Carlos M. Correa, "Pro-competitive measures under TRIPS to promote technology diffusion in developing countries", *Global Intellectual Property Rights: Knowledge, Access and Development*, Peter Drahos and Ruth Mayne, eds. (Palgrave Mcmillan, 2002).

exceptions include research and experimentation, with or without commercial intent, which is particularly important, taking into consideration scientific freedoms. They also include uses by third parties who can prove they were already using the technology before it was patented.[24] In the context of medicines, the early-working exception allows a generic producer to produce therapeutic equivalents and submit them for marketing approval to national drug regulatory authorities before the patent term has expired.

68. Article 31 allows countries to impose compulsory licenses for a very broad range of reasons. A compulsory license grants a third party permission to produce and market the patented technology without the consent of the patent-holder, so long as reasonable compensation is paid and certain formalities are followed. It is one mechanism through which Governments give precedence to the public's interest in having technical knowledge more immediately accessible. Article 31 does not specify the grounds for such licences, but rather establishes procedures that Governments must follow.[6]

69. Article 32 provides that an opportunity for judicial review of any decision to revoke or forfeit a patent shall be available. The TRIPS Agreement does not establish the grounds for revocation or forfeiture, which must be determined by national laws. States may contemplate revocation on grounds of public interest. Article 66 of the India Patent Act is one example of such legislation.[25]

70. Article 8 of the TRIPS Agreement specifies that States may adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of the Agreement. The WTO Doha Declaration on the TRIPS Agreement and Public Health, in paragraph 4, confirmed that the Agreement "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health" and to promote "access to medicines for all", and reaffirmed the right to use the Agreement's flexibilities for this purpose.

71. It is crucial that international legal regimes on patents continue to leave room for countries to adopt and implement policies to abide by their human rights obligations. New trade or investment treaties, whether bilateral or regional, already concluded or still under negotiation, considerably reduce that margin of manoeuvre. For example, the Trans-Pacific Partnership Agreement, involving 12 negotiating States, is said to require much stronger intellectual property protection than the TRIPS Agreement. Documentation also exists regarding the potential impact of concluded free trade agreements on public health.[26] Some observers stress that countries considering agreements like the Trans-Pacific Partnership or bilateral "partnership" agreements with the United States and Europe should be wary as "what are being sold as 'free-trade agreements' include intellectual property provisions that could stifle access to affordable medicines, with a potentially significant impact on economic growth and development".[4]

[25] Hans Morten Haugen, *The Right to Food and the TRIPS Agreement: With a Particular Emphasis on Developing Countries' Measures for Food Production and Distribution* (Leiden, The Netherlands, Martinus Nijhoff Publishers, 2007).

[26] UNAIDS and UNDP, *The Potential Impact of Free Trade Agreements on Public Health* (Geneva, 2012).

72. Although exclusions, exceptions and flexibilities are fully part of international intellectual property law, such as the TRIPS Agreement, they remain optional from the perspective of trade law. From the perspective of human rights, however, they are often to be considered as obligations.

B. Importance of public participation and transparency

73. Currently, considerable concern is being expressed that intellectual property policy-making in bilateral and multilateral forums tends to be conducted amid great secrecy, with substantial corporate participation but without similarly well-informed participation of elected officials and other voices representing the public interest. There is concern that international trade treaties are being used to drive and delimit domestic patent policies, short-cutting democratic processes and discussions and in contradiction to article 25 of the International Covenant on Civil and Political Rights, which protects the right of every citizen to take part in the conduct of public affairs, directly or through freely chosen representatives.[27]

74. Such concerns have been widely publicized recently by civil society groups around treaties currently under negotiations, in particular the Trans-Pacific Partnership Agreement (Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, United States of America and Viet Nam), and the Transatlantic Trade and Investment Partnership, involving the European Union and the United States).

75. The investor-state-dispute settlement chapters included in such agreements are likewise viewed as increasingly problematic, as they put at risk the regulatory function of many States and their ability to legislate in the public interest. The problem is aggravated by the "chilling effect" that intrusive investor-state-dispute settlement awards have, when States are penalized for adopting regulations, for example, to ensure access to generic and essential medicines.[27]

76. Research and development costs are usually forwarded by corporations to justify high prices for their patented products. Far more transparency about actual costs is needed.

C. Examples of good practices

77. Some WTO members use TRIPS flexibilities in favour of the right to benefit from scientific progress, particularly in the area of health. Among several public health sensitive flexibilities, section 3(d) of the amended 1970 Indian Patent Law provides a list of products not considered as "inventions", excluding from patentability, for example, new uses and most new forms of existing drugs. The provision led to the Novartis case, when the patent office refused to register a new form of Glivec, a drug used for treating blood cancer. In April 2013, the Supreme Court of India rejected the appeal of the company, which had failed to prove the improved therapeutic efficacy of the new version of a previously known substance.

[27] Office of the United Nations High Commissioner for Human Rights, "United Nations experts voice concern over adverse impact of free trade and investment agreements on human rights", 2 June 2015; available from http://www.ohchr.org/FR/NewsEvents/Pages/DisplayNews.aspx?NewsID=16031&LangID=E.

78. In 2013, the Supreme Court of the United States held that human DNA (isolated genes) could not be patented and that merely isolating genes found in nature does not make them patentable. The Court did, however, uphold the patents of the concerned company, Myriad Genetics, on the complementary DNA version of the genes, a synthetic creation not normally present in nature.[28]

79. Patient organizations, health activists and generic companies have used pre- and post-grant opposition systems to challenge patents applications as not satisfying patentability criteria in some countries. In Brazil, the Brazilian Health Surveillance Agency (ANVISA) has authority to require re-examination of patents on inventions that have important health implications.

80. Compulsory licensing has been initiated in countries such as Brazil, Ecuador, India, Indonesia, Malaysia and Thailand. Compulsory and government-use licenses have been issued for HIV/AIDS-related medicines, and for cardiovascular, cancer and hepatitis medicines. In addition, nearly 25 least developed countries have taken advantage of their TRIPS transition period with respect to pharmaceutical products to decline to enforce patents on medicines, thereby being able to import cheaper generic antiretroviral medicines to treat HIV and AIDS.

81. The Human Genome Project mapping the genetic information of human chromosomes, as a basis for future medical research, was proposed by the United States and became a global collaboration, with sequencing carried out by universities and research centres in several countries. The information generated by the project was put into the public domain and made available to all researchers without charge.[29]

82. The Medicines Patent Pool, supported by UNITAID, has negotiated in-licenses for 11 medicines from 6 patent holders and out-licenses to 10 generic manufacturers who can thereby supply cheaper generic antiretroviral drugs to the vast majority of people living with HIV and AIDS in low- and middle-income countries. This "collective management" of patent rights is an approach that might be extended to promote access to other medicines.

83. Databases have been created for the documentation and conservation of traditional knowledge, in an attempt to combat biopiracy. Interesting models include the 2004 National Commission against Biopiracy of Peru, which has prioritized 35 Peruvian biological resources of significant utility and potential value. The Commission has sent information to relevant intellectual property offices in third countries, contributing to decisions to reject, abandon or withdraw nine controversial patents utilizing Peruvian genetic resources and associated traditional knowledge. Notably, the Peruvian patent office took the lead in this exercise, as patent examiners are best situated to compile dossiers that help other patent offices to reach an informed decision.[14]

84. Many States have introduced a requirement that applications for patents for inventions based on genetic resources and/or associated traditional knowledge should disclose information about their source or origin, as well as on whether or

[28] See Supreme Court of the United States of America, *Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al.*, Decision of 13 June 2013, No. 12-398.

[29] See Heidi L. Williams, "Intellectual property rights and innovation: evidence from the human genome", *Journal of Political Economy*, vol. 121, No. 1 (February 2013); available from hdl.handle.net/1721.1/78858.

not they were accessed subject to prior and informed consent requirements, and used in accordance with mutually agreed terms for the fair and equitable sharing of the benefits arising therefrom.

85. Anti-trust competition laws may be used to impose limits on patents, for example, prohibiting patent holders from refusing to grant licenses without justification, forbidding the originator firm from buying out the generic manufacturers, or impeding firms' attempts to force patients to switch from a drug whose patent is about to expire to a newly patented drug.

86. Research institutes and universities have developed guidance tools to ensure that their licencing approaches are compatible with their primary mission to develop technology for the benefit of society. The Global Access Licensing Framework, developed by the Universities Allied for Essential Medicines, for example, can be used by producers and holders of intellectual property to develop policies allowing equitable access to their technologies, regardless of income.[30] Another tool developed by Stanford University, United States, recommends that universities, inter alia, reserve the right to practice licensed inventions and allow other non-profit and governmental organizations to do so; structure exclusive licenses in a manner that encourages technology development and use; ensure broad access to research tools and consider including provisions in licences that address unmet needs such as those of neglected patient populations or geographic areas.[31]

VI. Conclusions and recommendations

The Special Rapporteur makes the following conclusions and recommendations:

87. A model of access to technology based on individual ability to pay is rational and legitimate from a purely commercial perspective. From a human rights perspective, however, deprivations through patent exclusivity may be deemed as arbitrary, discriminatory or disproportionate, depending on the extent to which human rights interests are implicated by the specific technologies at stake, and the degree to which patent exclusivity, rather than production costs, create the high prices.

88. The human rights perspective focuses attention on important themes that may get lost when patents are treated primarily in terms of trade, as currently under the TRIPS Agreement: the social function and human dimension of intellectual property, the public interests at stake, the importance of transparency and public participation in policymaking, the need to design patent and alternative incentive regimes to promote research, creativity and innovation, the importance of broad diffusion of technological advances and scientific freedom, the importance of not-for-profit scientific production and innovation, and the special consideration for the impact of patent regimes upon marginalized and vulnerable groups.

89. The obligations of States under intellectual property treaties must not jeopardize the implementation of their obligations under human rights treaties.

[30] Available from http://uaem.org/global-access-licensing-framework/.

[31] See "In the public interest: nine points to consider in licensing university technology", March 2007; available from www.autm.net/Nine_Points_to_Consider1.htm.

Implementing unreasonably strong patent protection may constitute a violation of human rights. The human right to science and culture, as enshrined in article 27 of the Universal Declaration of Human Rights and article 15 of the International Covenant on Economic, Social and Cultural Rights, requires measures to ensure the affordability of and accessibility to technologies that are essential for a life with dignity and supporting the realization of other human rights. It includes a right to have access to and use technologies in self-determined and empowering ways.

90. **There is no human right to patent protection under article 15 of the International Covenant on Economic, Social and Cultural Rights. This provision does not obligate States parties to enact any particular form of patent protection. Patents are one policy tool among many for encouraging innovation and technological research and development. More caution is required in assessing their positive versus negative effects depending on the context and the technologies at stake. Human rights law operates as a limit to prevent the overreaching of economic claims by patent-holders in contexts where the rights to health, food, access to technology or other human rights would be compromised.**

91. **Particularly in areas characterized by high social need but low ability to pay, alternative policies for incentivizing technological development are important, but remain too scarce to meet human rights objectives, including the right to health. Models include government grants and procurements, advance purchase commitments, tax incentives for research and development, prizes and other means. These mechanisms should contain provisions on access and be empirically evaluated to gauge how well they meet the needs of the population.**

A. Ensuring transparency and public participation in law-making

92. **International intellectual property instruments, including trade agreements, should be negotiated in a transparent way, permitting public engagement and commentary.**

93. **National patent laws and policies should be adopted and reviewed in forums that promote broad engagement, with input from innovators and the public at large.**

94. **Companies benefitting from patents in the pharmaceutical sector should disclose information about the costs for developing drugs, the items included in such costs and the sums they reinvest in research and development.**

B. Ensuring the compatibility of patent laws, policies and practices with human rights

95. **International patent instruments should be subject to human rights impact assessments and contain safeguards for human rights, including the right to health, food, science and culture.**

96. **The WTO bodies should take into account human rights standards and obligations when interpreting WTO rules on intellectual property. They should review rules that have a negative impact on the realization of human rights.**

97. **States should complete a human rights impact assessment of their domestic patent law and policy.**

98. **National courts and administrative bodies should interpret international and national patent rules consistently with human rights standards.**

99. **States should allow non-governmental organizations, farmers' groups and other public interest groups, as well as government bodies, to challenge patents in pre- and post-opposition proceedings and in courts on the basis of public interest standing.**

100. **Patent laws should place no limitations upon the rights to health, food, science and culture, unless the State can demonstrate that the limitation pursues a legitimate aim, is compatible with the nature of this right and is strictly necessary for the promotion of general welfare in a democratic society (International Covenant on Economic, Social and Cultural Rights, art. 4). In all cases, the least restrictive measure shall be adopted.**

101. **In accordance with principle 11 of the Guiding Principles on Business and Human Rights, business enterprises should respect human rights and address any adverse human rights impacts resulting from their activities.**

C. Exclusions, exceptions and flexibilities

102. **In accordance with principle 9 of the Guiding Principles on Business and Human Rights, States should maintain adequate domestic policy space to meet their human rights obligations when pursuing business-related policy objectives with other States or business enterprises, for instance through investment treaties or contracts.**

103. **States have a positive obligation to provide for a robust and flexible system of patent exclusions, exceptions and flexibilities based on domestic circumstances, including through the establishment of compulsory and government use licences when needed.**

104. **States have a human rights obligation not to support, adopt or accept intellectual property rules, such as TRIPS-Plus provisions, that would impede them from using exclusions, exceptions and flexibilities and thus from reconciling patent protection with human rights. International agreements that do not provide sufficient flexibility should be renounced or modified.**

105. **States should refrain from pressuring other States to adopt TRIPS-Plus provisions or to otherwise forego the use of TRIPS-compliant flexibilities.**

106. **At the domestic level, judicial or administrative procedures should enable members of the public to request the implementation and expansion of exclusions, exceptions and flexibilities to assure their constitutional and human rights.**

107. **WTO members should ensure the exemption of least developed countries from complying with the TRIPS Agreement provisions until they reach a stage of development where they no longer qualify as least developed countries.**

D. Adopting policies fostering the right to science and culture, including the right to scientific freedom

108. **States and other stakeholders should explore, especially in the area of health and food security, systems that delink the costs of research and development from the price of products, in particular medicines.**

109. **Where scientific and technological research is subsidized by Governments, intergovernmental organizations or charitable entities, particular care must be taken within the funding structures and processes to ensure that the resulting technologies are made widely accessible.**

110. **States should invest in science, ensure independence for researchers, guarantee their freedom to publish results and their ability to continue to undertake research, to improve existing technologies and processes, and to be innovators in their own context for their survival needs, regardless of patents. Plant variety rules should not impede the right of small farmers to continue to use, save, exchange and sell farm-saved seeds and to continue to engage in experimentation, especially in situ.**

111. **Universities and other public research institutions play an important role. They should ensure that their licencing approaches are compatible with their primary mission to explore and develop technological innovations for the benefit of society. This role of universities and other public research institutions should be respected and protected.**

112. **States should do more to distinguish between generic medications and counterfeit medications. States through which generic medications transit have a responsibility to treat the generics in accordance with the law of the destination country.**

113. **As suggested by the Global Commission on HIV and the Law, the United Nations should convene a neutral, high-level body to review and assess proposals and recommend a new intellectual property regime for pharmaceutical products that is consistent with international human rights law and public health requirements, and simultaneously safeguards the justifiable rights of inventors.**

E. Indigenous peoples and local communities

114. **States should (1) ensure availability of legal measures and remedies to ensure the control by indigenous peoples and local communities over their biocultural heritage; (2) prohibit unethical and/or unlawful appropriation of the heritage of indigenous peoples and local communities through patents; (3) ensure appropriate credit and compensation; and (4) ensure that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the free, prior and informed consent or**

approval and involvement of these communities, and that mutually agreed terms have been established.

115. **Enhanced disclosure requirements in intellectual property legislation, such as sources, should be adopted to protect the right of attribution of communities whose traditional knowledge contributed to a patent application.**

116. **States should develop strategies to assist user countries in the assessment of patent applications that contain domestically sourced genetic resources or associated traditional knowledge. Ideally, intellectual property offices should take the lead in coordinated efforts among local stakeholders to develop dossiers on identified priority biological resources.**

Annex

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